APR 1 0 2002

K011524

510(K) SUMMARY

Date:

Contact Person:	David D. Dalise President/Owner, "O" Company, Inc.
Trade Name:	(ISD) Immediate Stabilizing Device
Common Name:	Endosseous Screw Implant
Classification Name:	Dental Implant Endosseous / Code 76DZE
Substantial Equivalence to:	Dentatus MTI (K980620) and Imtec Sendax MDI (K972351)
Description of Device:	A self-tapping CP Titanium or Titanium Alloy threaded screw, with light grit blasting or roughened surface treatment.
Intended Use:	The titanium endosseous implant is a device intended to be surgically placed in the bone of the upper or lower jaw arches to providing temporary support for transitional prosthetic devices, resulting in the restoration of the patient's chewing function. This device is intended for temporary use only and not for permanent implantation.
Substantial Equivalence:	Substantial Equivalence for the (ISD) implant is based on the following comparison of predicate devices such as Dentatus MTI and the Imtec's Sendax MDI. The design, function, labeling, material composition and intended use are equivalent to the devices currently on the market.

This data supports our determination that the Immediate Stabilizing Device (ISD) is Substantially equivalent to the Dentatus MTI K980620 and Imtec's Sendax MDI K972351.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2002

Mr. David D. Dalise
President
"O" Company Incorporated
600 Paisano, N.E., Suite A
Albuquerque, New Mexico 87123

Re: K011524
Trade/Device Name: Immediate Stabilizing Device (ISD)
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: January 4, 2002
Received: January 10, 2002

Dear Mr. Dalise :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011524

Device Name: Dental Implant Endosseous

Indications For Use:

The Immediate Stabilizing Device (ISD) is intended to be surgically placed in the bone of the upper or lower jaw arches providing temporary support for transitional prosthetic devices, resulting in the restoration of the patient's chewing function. This device is intended for temporary use only and not for permanent implantation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011524